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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/635,276 08/09/00 DEES

H PHO-113

HM12/1106
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EXAMINER

EPPS, J

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 11/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/635,276	Applicant(s) DEES ET AL.	
	Examiner Janet L. Epps	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: _____

WILLIAM N. PHILLIPS
PATENT ANALYST

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Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.7572262247

The oath or declaration is defective because:

It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

In the first paragraph of the specification as filed it states "This application claims benefit of 60/149,015 filed August 13, 1999 which is a continuation-in-part of USSN 08/989,231." This is improper since according to MPEP § 201.07 "[A]n application claiming the benefits of a provisional application under 35 U.S.C. 119(e) should not be called a "continuation" of the provisional application since an application that claims benefit of a provisional application is a nonprovisional application of a provisional application, not a continuation, division, or continuation-in-part of the provisional application."

If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application, additionally the status of nonprovisional parent application(s) (whether patented or

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abandoned) should be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Claim Objections

3. Claims 12 and 20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case claims 12 and 20 recite "wherein said green light has a wavelength of between approximately 500 nm and 600 nm." This limitation does not further limit either claim 11 or claim 19 since this limitation is a normally occurring characteristic of green light.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6-10, 13-16, 26-29, 33 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13-16 provide for the use of a halogenated xanthene in the preparation of a medicament, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where

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it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 13-16 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 6 and 26 recite multiple "amino acids, proteins, antibodies.....and other hydrophilic or hydrophobic moieties." The limitations recited in the Markush group of claim 6, other than the terms DNA and RNA are presented in plural form, it is unclear if the claim is drawn to one or multiple amino acids, proteins, antibodies, and etc. Applicants are invited to amend the instant claim to clearly distinguish whether the claim is to be drawn to one or multiple inventions. By convention claims are normally directed to one invention. Additionally, the Markush group recited in Claims 6 and 26 is also vague and indefinite since the elements of a Markush group are intended to be mutually exclusive, in the instant case it appears that the term "ligand" for example, encompasses all other members of the Markush group. The "term proteins" recited in this claim would also encompass multiple elements in the Markush group, for example, protein receptors, carbohydrate receptors, ligands, haptens, carbohydrate receptors, etc.

Claims 7-10, 14, 26-29, and 37 recite improper Markush groups, each Markush recited in the cited claims comprise plural elements, wherein it is unclear if Applicant's claims are directed to one or multiple inventions. For example, claim 7 recites "selected from the group consisting

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of liquids, semisolids, solids, and aerosols.” It is unclear if the delivery vehicle recited in claim 7 consists of one or multiple “liquids, semisolids, solids and aerosols.” Amending claim 7 to recite for example: “selected from the group consisting of a liquid, semisolid, solid, and an aerosol,” would likely obviate this rejection.

Claims 10, 33, and 37 recite the terms “conditions affecting” and/or “related organs.” The metes and bounds of these terms are vague and indefinite since it is unclear how one of ordinary skill in the art would be reasonably apprised as to the scope of the terms “affecting” and/or “related” as used in this context.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 5-6, 11-14, 16-17, 19-22, 25-26, and 30-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaboury et al. (US Patents 5,556,992 and 5,773,460).

Gaboury et al. (US 5,556,992, and US 5,773,460; col. 5, lines 5-30) provide a method for the complete growth inhibition of tumor cell lines in vitro after photodynamic therapy effected with the photosensitizers. These photosensitizers include halogenated xanthene compounds such as photoactivable rhodamine derivatives for enhancing high quantum-yield production and singlet oxygen generation upon irradiation while maintaining desirable differential retention of rhodamine between normal and cancer cells, said derivatives are selected from the group

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consisting of 4,5-dibromorhodamine 123 (2-(4,5-dibromo-6-amino-3-imino-3H-xanthen-9-yl)-benzoic acid methyl ester hydrochloride); 4,5-dibromorhodamine 123 (2-(4,5-dibromo-6-amino-3-imino-3H-xanthen-9-yl)-benzoic acid ethyl ester hydrochloride); 4,5-dibromorhodamine 123 (2-(4,5-dibromo-6-amino-3-imino-3H-xanthen-9-yl)-benzoic acid octyl ester hydrochloride); 4,5-dibromorhodamine 110 n-butyl ester (2-(4,5-dibromo-6-amino-3-imino-3H-xanthen-9-yl)-benzoic acid n-butyl ester hydrochloride); Rhodamine B n-butyl ester (2-(6-ethyl amino-3-ethyl imino-3H-xanthen-9-yl)-benzoic acid n-butyl ester hydrochloride); and photoactivable derivatives thereof. Photoactivation of these derivatives induces cell killing while unactivated derivatives are substantially non-toxic to cells.

Garbory et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

8. Claims 1, 4-12, 21, and 24-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Kopia et al.

Kopia et al. disclose a composition comprising Fluorescein isothiocyanate (FITC) conjugated goat anti-rabbit antibody (see col. 52, lines 31-33). This composition corresponds to Applicant's claimed medicament comprising at least one halogenated xanthene compound, Fluorescein, and further comprising at least one targeting moiety, an anti-rabbit antibody. Pharmaceutical preparations comprising compounds of the invention may be conveniently formulated for administration with a compatible biological medium, such as salt-free isotonic solutions, or pharmaceutically acceptable liquid excipients. The latter include various inert oils, e.g., vegetable oils such as olive oil or peanut oil, or highly refined mineral oil. The

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concentration of active ingredient in the chosen medium will vary, depending on the nature of the compound and the disease or pathological condition being treated (col. 33, lines 30-39).

Kopia et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 2-4, 7-10, 15, 18, 23-24, 27-29, and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaboury et al. (US Patents 5,556,992 and 5,773,460).

The discussion of the Gaboury et al. patents set forth above is included here. However, the Gaboury et al. patents do not recite the exact halogenated xanthene compounds recited in the instant claims, or the concentrations of halogenated xanthene used in the medicaments of the present invention. Although, the compounds of Gaboury et al. and those recited in the instant

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claims are not identical, the compounds of Gaboury et al. are halogenated xanthene compounds and are disclosed as useful for the same purposes as Applicant's compounds.

See MPEP § 2144.08 II.A.4.(c) which states that " If such a species or subgenus is structurally similar to that claimed, its disclosure may motivate one of ordinary skill in the art to choose the claimed species or subgenus from the genus, based on the reasonable expectation that structurally similar species usually have similar properties. See, e.g., Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214. Moreover, it states that "[S]tructural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties.").

Since the halogenated xanthene compounds of Gaboury et al. are structurally similar to the compounds of the instant invention and are disclosed as useful in the same processes as those recited in the instant claims, particularly for use in photodynamic therapy, it would have been obvious to one of skill in the art at the time of filing to use derivatives of halogenated xanthene in a method of photodynamic therapy.

Furthermore, although Garboury et al. does not disclose the same percent concentration of halogenated xanthene used in the medicaments of the present invention, the recitation of a specific percent, ratio or range does not render any patentable weight if the prior art discloses the claimed compositions, absent evidence of unexpected results with regards to the claimed range, percent or ration. See MPEP § 2144.05 which states that "[G]enerally, differences in

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concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

“[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Therefore, the invention as a whole would have been prima facie obvious at the time of filing over Gaboury et al.

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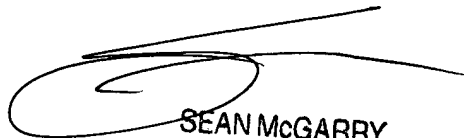
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps
Examiner
Art Unit 1635

JLE
November 5, 2001


SEAN MCGARRY
PRIMARY EXAMINER